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| 09/702,037 | 10/27/2000 | Peter Bennett Duff Whyte | U013032-6 | 8344 |

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08/13/2002

EXAMINER

WARE, DEBORAH K

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| ART UNIT | PAPER NUMBER |
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1651

DATE MAILED: 08/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/702,037

Applicant(s)

Whyte

Examiner

Deborah Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 5, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above, claim(s) 5-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 11-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2413 6) ☐ Other:

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Claims 1-27 are presented for examination on the merits.

The Power of Attorney filed April 25, 2002, has been received and entered. Also the extension of time and election filed May 20, 2002, have been received and entered. Further, the IDS (information disclosure statement) filed August 5, 2002, has been received and entered. In addition, the IDS filed December 1, 2000, and preliminary amendments filed October 27, 2000, have been received and entered as well. Further, as Applicants are most likely aware of the petition filed under 37 CFR 1.47 on July 2, 2001, was granted on October 31, 2001.

The references submitted with the IDS(s) have been considered as indicated on the enclosed copies of the PTO-1449 Forms.

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119 (a)-(d). The certified copy has been filed in parent Application No. PCT/AU99/00317, filed on April 30, 1999. The foreign priority date is April 30, 1998.

This application is a continuation of PCT/AU99/00317 filed April 30, 1999.

2. Applicant's election without traverse of Group I, claims 1-4 and 11-27 in Paper No. 12 is acknowledged. The election is being treated without traverse, although it is noted that Applicant did elect with traverse, no arguments were presented. However, Applicants rights to file one or more divisional applications directed to subject matter of claims 5-10 is acknowledged. Claims 5-10 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was

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made technically with traverse in Paper No. 12, but no arguments were presented so the election is being treated without traverse.

Claims 1-4 and 11-27 are examined on the merits.

3. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-Reference to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
- (e) Background of the Invention.
 - 1. Field of the Invention.

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2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

Further, it is suggested that in the specification IGF-1 and other abbreviations should be initially defined to ensure that their meaning as recognized in the art is intended. This is merely a suggestion and Applicant's cooperation is appreciated.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4 and 11-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1-4 provide for the use of a food composition in changing body composition and/or physical work capacity, but, since the claims do not set forth any steps involved for the use, it is unclear what process Applicant is intending to encompass. A claim is indefinite where

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it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It is suggested to merely delete "use in" at line 1 of claim 1. In addition, it is suggested to change "including" to --comprising-- since the examiner thinks the term "comprising" would read better in the claim 1. The term "comprising" in place of "including" at line 1 of claim 2 is also suggested only if the change is made in claim 1 at line 2. However, the language "maintained therein following fractionation of the colostrum" recited at line 3-4 in claim 1 is rendered vague and indefinite since it is unclear how the growth factors are being maintained and what exactly does the term "therein" mean with respect to the maintenance of the growth factors. Does the claim intend to mean that growth factors are in the colostrum since the growth factors are derived from colostrum? The metes and bounds of the claims can not be determined because it is not clear what is being maintained. Claim 4 is also rejected for similar reasons for the same type of language with respect to "and maintained therein following fractionation of the colostrum". Perhaps the growth factors are produced by the colostrum during fractionation, maybe this is what the language is intended to mean in the claims, however, clarification is requested.

7. Also claims 1-4 and 11 are rendered vague and indefinite since it is unclear what is intended by "changing body composition and/or physical work capacity" does this mean changing body fat, muscle tone, etc. Also what type of physical work capacity, lifting weights, or does this simply refer to body physics in terms of how WORK (W) is defined in the field of physics with respect to the human body? Clarification is also requested here. Also the step of

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"administering" is unclear and indefinite for claims 11-27 since it is uncertain how the process step of "administering" is being carried out per se. Perhaps since it is a food composition it is being eaten or perhaps it is fluid and administered via a drink or beverage of some sort. Further, the term "including" is used in place of "comprising", however, as suggested above "comprising" seems to be a better term for these types of claims, but again this is merely a suggestion. Also the term "physiological perception" is vague and indefinite since it is uncertain what exactly is intended to be encompassed within the meaning of the term. For example, does the term refer to behavioral responses as a function of a physiological perception? What exactly does the term mean in the claim. It is suggested to delete the term or clarify please. Claim 18 is rendered vague and indefinite for reciting improper Markush type language wherein the term "including" should be --consisting of-- since a Markush group should utilize closed terms. Also it is uncertain what the term "normal" as it refers to "patients" per se means in the claim. Perhaps this means patients not infected with HIV/AIDS? Further, regarding claim 18, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). In addition, the usage of the terms "peak power" and "peak force" is uncertain as to what the intended meaning is in the claim 24. Furthermore, claim 27 is rendered vague and indefinite for how "bioavailability of components in colostrum" are improved per se? What constitutes "improving"? The method is not clear as to what the intended improvement is really, other than bioavailability. Does this mean making the components more accessible to the human body or what? If so how is a method of improving

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measured in terms of bioavailability of components in colostrum with respect to the human body in vivo or is the "improving" effect something observed in the colostrum upon fractionation? Other claims "improving" claims have similar clarity problems with respect to their "improving" effects. Note other claims 21, 23, and 24. Perhaps these should be rewritten in Jepson type format wherein the improvement would be clearly set forth in the claims.

Furthermore, claims 1-4 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). The above noted suggested amendment to claim 1 would overcome this rejection under 35 USC 101 as well.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5,500,329 9. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Aalto et al. (A).

The claims are drawn to a composition comprising colostrum or a fraction thereof,

wherein the fraction includes IGF-I and the composition may include casein of which is colostrum derived and maintained therein following fractionation of the colostrum.

PTO-892
Form

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3- for 1 & 3 only

Aalto et al. teach a composition comprising colostrum or a fraction thereof, wherein the fraction includes IGF-I and the composition may include casein of which is colostrum derived and maintained therein following fractionation of the colostrum. Note column 1, lines 10-15 and 50-55 and column 2, lines 1-6 and column 5, lines 4, 7-8 and 17-20. Bovine colostrum contains caesin and fractions of bovine colostrum containing casein may be desirable as disclosed by the cited reference. Also bovine colostrum may be frozen at the farm and further contains growth factors such as IGF.

The claims are identical to the teaching of Aalto et al. and are therefore, considered to be anticipated by the teachings of this cited reference. Each of the claimed features of the composition are disclosed. The claims are identical to the disclosure of Aalto et al., cited on the enclosed PTO-892 Form.

10. Claims 17-18 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by AU-A-39340/89, Borody et al., cited on the enclosed PTO-1449 Forms.

Claims drawn to a method of treating or preventing a disorder of the gut wherein the disorder is caused by several different things, one of which is infections resulting from HIV. Treatment includes administering composition comprising colostrum. Also drawn to improving gut growth and performance. Also treating small bowel syndrome.

The reference teaches a method of treating or preventing a disorder of the gut wherein the disorder is caused by several different things, one of which is infections resulting from HIV. Note page 1-2, all lines. Also note pages 3-4, all lines. Colostrum is administered. Further,

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small bowel syndrome is treated with the colostrum, see page 1, lines 15-20. Further, gut growth and performance are disclosed.

The claims are identical to the cited reference and are, therefore, considered to be anticipated by the teachings of the cited reference.

11. Claims 14, 16, 19 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/10192, cited on the enclosed PTO-1449 Form.

Claims are drawn to a method of increasing recovery after exercise, improving peak power or peak force, and increasing endurance exercise performance by administering food composition of claim 1. Also drawn to method of reducing fatigue, muscle damage and increasing vertical jump using composition of claim 1

The reference teaches the same, note page 1, lines 1-5, see page 2, all lines and the abstract.

The claims are identical to the cited reference and are therefore considered to be anticipated by the teachings of the cited reference.

12. Claims 11-13, 15, 20, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark, 1996, cited on the enclosed PTO-1449 Forms.

Claims drawn to methods of changing body composition, increasing tissue mass, increasing fat utilization, increasing height, increasing physiological buffering capacity, reducing fat mass and improving bioavailability of components in colostrum by administering the composition of claim 1, colostrum.

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Clark teaches colostrum stimulates bone and muscle growth and nerve regeneration, increase body weight of lean muscle, protects against the bacteria that cause stomach ulcers, etc., note first few pages, both columns and all lines.

The claims are identical to the cited disclosure and are considered to be anticipated by the teachings of the cited reference. Increasing tissue mass and change of body composition are inherent to the teachings that muscle growth occurs with colostrum because tissue mass would inherently increase as would fat utilization, and changing body composition and reduction in fat mass and an overall improvement of bioavailability. Further, buffering capacity would inherently increase since the reference teaches that colostrum protects against the bacteria that cause ulcers. Ulcers reduce buffering capacity. Further, height would inherently increase since colostrum is taught to stimulate bone and muscle growth.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware

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August 10, 2002